

## REMARKS

Claims 1-8 and 10-20 were pending prior to the issuance of the Office Action mailed October 17, 2007. In this Response, Applicant amends Claims 1, 4 and 11 and Claims 14-20 are withdrawn as being directed to a non-elected invention. Basis for the claim amendments can be found throughout the specification or originally filed claims and do not introduce any new matter.

### *Claim Objections*

In the Non-Final Office Action mailed October 17, 2007, the Examiner stated Claim 1 was objected to because of informalities. Specifically, the Examiner objected to a lack of explicit connection linking release of haem moieties from beads in step (c) and subsequent detection in step (d). Applicant respectfully submits that Claim 1 is amended herein to explicitly link the release of haem moieties from the analyte in step (c), with subsequent detection of the released haem moieties in step (d). Accordingly, applicant respectfully submits he has overcome the objection and request its withdrawal.

### *Rejection of the Claims under 35 U.S.C. §112, second paragraph*

In the Office Action issued October 17, 2007, the Examiner rejected Claims 1-8 and 10-13 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject which applicants regard as the invention. Applicant respectfully submits that amendments to the claims overcome the rejection.

Applicant has amended Claim 1 to recite that in step (c), the alkaline conditions are **sufficient to release the haem moiety from the analyte, and thereby from the one or more magnetic beads, but not to extract inorganic iron from the one or more magnetic beads**. Support for the above amendment can be found on, at least, page 3, lines 7-9; and page 2, lines 20-23 of the published PCT application.

Additionally, Claim 1 is amended in step (d) to recite “**detecting the released haem moiety, and thereby detecting the analyte containing the haem moiety**, using a

luminal chemiluminescent assay procedure.” Support for the above amendment can be found on at least, page 1, lines 3-5 of the published PCT application.

Applicant respectfully submits that the claimed method is for detecting **an analyte containing a haem moiety**, and not just an analyte *per se*. In particular, the analyte (containing a haem moiety) is captured on magnetic beads and **isolated** from the sample prior to subjecting the **isolated** analyte (containing a haem moiety) to alkaline conditions. Consequently, any haem released by the alkaline conditions must have been contained within the **isolated** analyte (containing a haem moiety), and thus an explicit connection between the haem moiety and the analyte (containing a haem moiety) exists. Claim 1 has been amended to further stress this relationship, and to clarify that the haem moiety is released from both the analyte and thereby the beads.

Applicant respectfully submits that amended Claim 1 recites an active method step in which the analyte is detected. For at least the foregoing reasons, applicant respectfully submits that the amendments provided herein overcome the rejection under 35 U.S.C. §112, second paragraph, and kindly requests withdrawal of the claim rejection.

***Rejection of the Claims under 35 U.S.C. §103(a)***

In the Office Action issued October 17, 2007, the Examiner rejected Claims 1-3, 5, 8 and 10-12 under 35 U.S.C. §103(a), as being unpatentable over Ewetz *et al.*, (Anal Biochem (1976) April, 71(2) 564-70) in view of Hixson *et al.*, (WO 98/54578). Applicant respectfully submits that amendments to the claims overcome the rejection.

Applicant submits that Claim 1 is amended herein to recite that in step (c) the alkaline conditions are **sufficient to release the haem moiety from the analyte**, and thereby from the one or more magnetic beads, **but not to extract inorganic iron from the one or more magnetic beads**. Support for the above amendment can be found on, at least, page 3, lines 7-9 of the published PCT application.

Applicant respectfully submits that he discovered that the features of magnetic bead separation, release of haem (iron) from analytes containing a haem moiety, and a

sensitive iron-based detection assay can, **surprisingly**, be combined to produce a method capable of successfully detecting haem **without inorganic iron being extracted from the magnetic beads**, and thus without interference from inorganic iron (see page 1, line 28 - page 2, line 30 of the instant application).

Applicant respectfully submits that the amendments to Claim 1 incorporate the above limitations, and that the ability to release haem moieties from an analyte without inorganic iron being extracted from magnetic beads (steps (c) and (d) of amended Claim 1) is novel and non-obviousness over the prior art.

Specifically, applicant submits neither Ewetz *et al.* or Hixson *et al.* addresses the problem of iron release from magnetic beads, and especially not the specific problem of the present application - release of haem moieties from an analyte whilst avoiding extraction of inorganic iron from magnetic beads.

Moreover, though the features of magnetic separation, release of haem moieties, and sensitive iron based assays are found separately in the cited prior art there is **no motivation, teaching or suggestion** in any of the documents to **combine** these features. Applicant respectfully submits that, based on the prior art and in light of common knowledge to those of ordinary skill in the art that luminol chemiluminescent procedures are very sensitive to inorganic iron contamination (see for example, page 1 line 28 - page 2 line 8 of the present application), together with the fact that inorganic iron is expected to be extracted from magnetic beads under alkaline conditions, one of ordinary skill would be directed to **actively avoid combining** alkaline conditions to release haem moieties **and** magnetic bead capture. Applicant respectfully submits that one of ordinary skill in the art would not therefore be motivated to combine magnetic bead capture and alkaline conditions because it leads to inorganic iron contaminants that can produce false negative or false positive results in a luminol chemiluminescent assay.

Applicant respectfully submits Claims 2-3, 5, 8 and 10-12 depend directly or indirectly on amended Claim 1 and are therefore novel and non-obvious over the cited prior art.

For at least the foregoing reasons, Applicant respectfully submits he has overcome the rejection of Claims 1-3, 5, 8 and 10-12 under 35 U.S.C. §103(a), and requests its withdrawal.

In the Office Action issued October 17, 2007, the Examiner rejected Claim 4 under 35 U.S.C. §103(a), as being unpatentable over Ewetz *et al.* (already of record) in view of Hixson *et al.* (already of record) as applied to Claim 1 above, and further in view of Valkirs *et al.* (US 6,503,722). Applicant respectfully submits that the amendments to the claims overcome the rejection.

As stated above, Applicant submits that neither Ewetz *et al.* or Hixson *et al.* provide a motivation, teaching or suggestion to release haem moieties from an analyte while avoiding extraction of inorganic iron from magnetic beads, as recited in amended Claim 1. The deficiencies of Hixson *et al.* and Ewetz *et al.* are not satisfied by Valkirs *et al.* for at least the following reasons.

Valkirs *et al.* fail to address the problem of iron release from magnetic beads, and especially not the specific problem of the present application - release of haem moieties from an analyte while avoiding extraction of inorganic iron from magnetic beads. Applicant respectfully submits that Valkirs *et al.* provides **no motivation or teaching** to derive the claimed method. As discussed above, based on the prior art and common knowledge to one of ordinary skill in the art, applicant respectfully submits that one of ordinary skill would not be motivated to combine magnetic bead capture and alkaline conditions so as not to produce **inorganic iron contaminants** that can adversely affect the luminol chemiluminescent assay.

For at least the foregoing reasons, applicant respectfully submits he has overcome the rejection of Claim 4 under 35 U.S.C. §103(a), and requests its withdrawal.

In the Office Action issued October 17, 2007, the Examiner rejected Claim 13 under 35 U.S.C. §103(a), as being unpatentable over Ewetz *et al.* (already of record) in view of Hixson *et al.* (already of record) as applied to Claim 1 above, and further in view of Wang *et al.* (US 5,431,793). Applicant respectfully submits that amendments to the claims overcome the rejection.

As stated above, Applicant submits that neither Ewetz *et al.* or Hixson *et al.* provide a motivation, teaching or suggestion to release haem moieties from an analyte while avoiding extraction of inorganic iron from magnetic beads, as recited in amended Claim 1. The deficiencies of Hixson *et al.* and Ewetz *et al.* are not satisfied by Wang *et al.* for at least the following reasons.

Wang *et al.* fails to address the problem of iron release from magnetic beads, and specifically not the problem of the present application - release of haem moieties from an analyte while avoiding extraction of inorganic iron from magnetic beads. Applicant respectfully submits that Wang *et al.* provides **no motivation or teaching** to derive the claimed method. As discussed above, based on the prior art and common knowledge to one of ordinary skill in the art, applicants respectfully submit that one of ordinary skill would be directed to **actively avoid combining** magnetic bead capture and alkaline conditions so as not to produce inorganic iron contaminants.

For at least the foregoing reasons, applicant respectfully submits he has overcome the rejection of Claim 13 under 35 U.S.C. §103(a), and request its withdrawal.

In the Office Action issued October 17, 2007, the Examiner rejected Claims 1-2, 4, 6-8 and 13 under 35 U.S.C. §103(a), as being unpatentable over Bruno *et al.* (Appl Environ Microbio (1996) Sept; 62(9):3474-3476) in view of Valkirs *et al.* (already of record), Giaever *et al.* (US 3,970,518) and Heroux *et al.* (US 2002/0146722). Applicant respectfully submits that amendments to the claims overcome the rejection.

As stated above, Valkirs *et al.* fail to provide motivation, teaching or suggestion to release haem moieties from an analyte while avoiding extraction of inorganic iron from magnetic beads, as recited in amended Claim 1.

Similarly, Bruno *et al.*, Giaever *et al.*, and Heroux *et al.* all fail to address the problem of iron release from magnetic beads, and specifically ignore the problem of the present application - release of haem moieties from an analyte while avoiding extraction of inorganic iron from magnetic beads. Applicant respectfully submits that **none of the cited references provide motivation or teaching to derive the claimed method**. As discussed above, based on the prior art and common knowledge to one of ordinary skill in the art, applicant respectfully submits that one of ordinary skill would not be motivated to combine magnetic bead capture and alkaline conditions so as not to produce **inorganic iron contaminants** that can adversely affect the luminol chemiluminescent assay.

For at least the foregoing reasons, applicant respectfully submits he has overcome the rejection of Claims 1-2, 4, 6-8 and 13 under 35 U.S.C. §103(a) and requests its withdrawal.

### CONCLUSION

Applicant respectfully submits this Response is fully responsive to the Office Action mailed October 17, 2007. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by an Examiner's amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404) 815-6473 is respectfully solicited.

Respectfully submitted,

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